REMARKS

Claims 1 – 10, 13 – 22, 25, 30 and 31 are in the case.

Claims 1, 25 and 30 are amended herewith to recite Type A gelatin. Basis is submitted to be found in paragraphs [0013] and [0034] and [0035] of the corresponding patent application publication.

Claim 30 is amended herein to recite the kind of neoplastic diseases treatable by the invention. Basis is submitted to be found in paragraph [0023] of the corresponding patent publication.

We turn now to the rejections.

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph on the basis that prophylaxis is not enabled, relying on Ex Parte Forman, 230 U.S.P.Q. 546,547 (Bd. App. and Int. 1986) and In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (CAFC 1988) and administering the Wands factors. Reconsideration is requested.

The PTO position is defective because the Office Action does not apply any of the Wands factors and more importantly because the law is that applicant does not have to prove or show that the invention is effective for prophylaxis. Rather the burden of proof is on the PTO to prove that the treatment as claimed is not effective for prophylaxis. See Ex parte Reese, 40 U.S.P.Q.2d 1221 (Pat. Off. Bd. App. Int. 1996); In re Dinh-Hguyen, 181 U.S.P.Q. 46,47 (C.C.P.A. 1974) and In re Gardiner, 177 U.S.P.Q. 396, 397 (C.C.P.A.). The PTO has not met this burden.

Moreover, application of the Wands factors for facts different from those in Wands does not cause the burden in the PTO to change to Applicant. No case says that such does.

The Wands factors are directed to showing lack of enablement for the facts of Wands as described in In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Consider also Ex Parte Forman, 230 U.S.P.Q. 546,547 (Bd. App. and int. 1986) relied on by Wands for the Wands factor.

The specific issue in Wands involved whether monoclonal antibodies necessary

experimentation when practice involved unpredictable result screening negative hybridomas to find those that produced the desired antibodies.

In Foreman a question was whether mutant strains of S. typhis necessary for an oral vaccine were enabled when there was a lack of guidance leading to predictable results for obtaining mutant S. typhis.

The instant case differs from Wands and Foreman because no issue has been raised about treating agents or treating regimen. Thus the specific issues present in Wands and Foreman are not present here.

The issue according to Wand and Foreman is whether the application here describes what to administer and how to administer it. There is no contention that it does not.

Moreover, the issue in the Office Action is directed at the operation of omega-3 polyunsaturated fatty acid in free acid (PUFA) form while the invention is directed at the effect of a particular capsule on this. The issue has not been raised that the capsule destroys the utility of PUFA. The utility of PUFA for prophylaxis is recognized; see claim 1 at U.S. 5,502,777. Thus the proof the PTO is requiring is already there.

In another rejection, claims 30-31 are rejected under 35 U.S.C. 112, second paragraph, for failing to comply with the enablement requirement for treating cancer broadly. In response claim 30 is amended to defined the neoplastic diseases referred to as one treatable by the administration of omega-3 polyunsaturated fatty acid and an antineoplastic agent selected from the list provided at [0023] of the corresponding published application. Reconsideration is requested.

In still another rejection, claims 1-20 are rejected for obviousness-type double patenting over claims 2-20 of 11/411,236. The claims of 11/411,236 relate to a sleep inducing composition and a method for producing such and are submitted to be irrelevant here and perhaps mistakenly residual from another Office Action. Reconsideration is requested.

In yet another rejection, claims 1-10 and 13-22 and 30-31 are rejected for obviousness-type double patenting over claims 1-17 of U.S. Patent No. 5,792,795 and

in another case apparently over claims of U.S. Patent No. 5,948,818.

Tillotts, the assignee of the instant application, is indeed the proprietor of U.S. Patent No. 5,792,795 and U.S. Patent No. 5,948,818, and both of these earlier U.S. patents do indeed claim soft gelatin capsules containing PUFAs in free acid form. However, the characterizing feature of these earlier inventions is the *coating* for the capsules which controls release of the capsule contents. In contrast, the present invention is based on the unexpected observation that soft gelatin capsules containing PUFAs in free acid form in which the gelatin is Type A gelatin are significantly more stable (and, hence, have a significantly greater shelf life) than equivalent capsules made from Type B gelatin. Thus, the characterizing feature of the present invention is the specific choice of gelatin from which to make the soft gelatin capsules.

Both U.S. Patent 5,792,795 and U.S. Patent No. 5,948,818 disclose that the oral dosage form may be a *soft* gelatin capsule. However, there is no disclosure in either reference of any particular *type* of gelatin, let alone Type A gelatin. Since there is no clear and unambiguous disclosure in either of these references of encapsulating PUFAs in *free acid form* using *Type A* gelatin, the present invention is not anticipated by these references.

Regarding inventive step, both U.S. Patent 5,792,795 and U.S. Patent No. 5,948,818 are entirely silent on the issue of stability of soft gelatin capsules containing PUFAs in free acid form. The silence is not surprising when one considers that the client only recognized that there was an issue with stability long after these earlier applications had been filed. It is acknowledged that both references disclose the possibility of encapsulating PUFAs in free acid form in soft gelatin capsules. However, such embodiments are entirely speculative as, at that time, only *hard* gelatin capsules had been used by the client and, hence, only hard gelatin capsules are exemplified in these references. The stability issue only became apparent after the client switched its attention to soft gelatin capsules which, again, was only after the earlier applications had been filed.

As acknowledged in the present application, the skilled person would have been

aware at the priority date (February 2004) of the present invention that there are two types of gelatin, Type A gelatin and Type B gelatin, and that either form of gelatin could be used to make the soft gelatin capsules disclosed in the references.

The technical effect of the use of Type A gelatin in place of Type B gelatin to form the soft free acids in the formulation is drastically reduced resulting in a substantial increase in the shelf life of the capsules. The problem addressed by the present invention is, therefore, how to improve soft gelatin capsules containing PUFAs in free acid form by reducing the rate of hardening of the capsules and thereby increasing the shelf life. The solution provided by the present invention is to use Type A gelatin to make the soft gelatin capsules.

Since Type A gelatin and Type B gelatin have basically the same chemical structure (in that the amino acid residues in both types of gelatin are essentially identical), the skilled person would have expected that soft gelatin capsules formed from each type of gelatin would harden at about the same rate following exposure to a given pharmaceutical formulation content. It is, therefore, entirely unexpected that the use of Type A gelatin should reduce the rate of hardening of the capsules at all, let alone to the substantial extend observed (see Example).

From the information he had at hand, the skilled person could not possibly have predicted before the priority date of the present invention, that the use of Type A gelatin would have such a beneficial effect on the shelf life of the capsules. The invention is, therefore, not obvious over either of the two earlier Tillotts references when considered alone. In addition, neither U.S. Patent No. 5,502,077 nor any other prior art reference of which the inventors are aware suggests that using Type A gelatin to form the soft gelatin capsules would reduce the hardening rate of the capsules. Therefore, the present invention also has an inventive step over the disclosure of either of the earlier Tillotts references when considered in combination with U.S. Patent No. 5,502,077 or other prior art of which the inventors are aware.

On this basis, the present invention is also <u>not</u> obvious over the earlier Tillotts patent. Reconsideration is requested.

In yet another rejection, claims 1-10, 13-22, 25 and 30-31 are rejected under 35 U.S.C. 103(a) as being obvious over Brievik et al. U.S. Patent No. 5,502,077.

Reconsideration is requested.

While Brievik does indeed disclose encapsulating PUFAs in free acid form in soft gelatin capsules, there is no disclosure in this reference of the use of any particular type of gelatin, let alone Type A gelatin.

As there is no disclosure of the use of any particular type of gelatin for the soft gelatin capsules, it is not surprising that U.S. Patent No. 5,502,077 is also silent on the issue of stability of soft gelatin capsules containing PUFAs in free acid form. Thus, when present with the problem of improved the stability of such capsules, he would not consider this reference as it does not address the same problem and even in the unlikely event that he did consider the reference, it does not disclose the solution proposed by the present invention.

It is noted that, where the form of the PUFA is specified in the examples in U.S. Patent 5,502,077, it is indicated as the ethyl ester rather than the free acid. In the remaining examples, the form of the PUFA is not specified. Therefore, there is no clear and unambiguous disclosure in the examples of a soft gelatin capsule containing a PUFA in free acid form and, if the remaining examples did not actually use the free acid form of the PUFAs, then the issue of stability of the soft gelatin capsules over time could not have become apparent.

The examiner has indicated that U.S. Patent No. 5,502,077 discloses the use of collagen as a pre-treatment source although he cited column 9, Table 10 as a reference to this feature. This reference is not a reference to the source of collagen from which the gelatin of the capsules is made. In contrast, this reference is to a feature of the method by which the blood platelet aggregating effect was measured. However, nothing would appear to turn on this point as the skilled person would have been aware that gelatin is obtained from a collagen source in any event.

It is additionally submitted that the claims are patentable over Brievik et al. because as indicated above, there is an entirely unpredictable increase in stability from the use of Type A gelatin over the use of Type B gelatin and Brievik doesn't mention Type A gelatin or make obvious this advantage.

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Date: April 10, 2008